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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,560	03/18/2004	Tami Harel	34487	7075

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EXAMINER	
KAHELIN, MICHAEL WILLIAM	
ART UNIT	PAPER NUMBER
3762	
MAIL DATE	DELIVERY MODE
03/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/804,560	HAREL ET AL.	
	Examiner	Art Unit	
	MICHAEL KAHELIN	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52-55,79-87,101 and 102* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52-55,79-87,101 and 102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 52-54, 79, 81-86, 101, and 102 are rejected under 35 U.S.C. 102(a/e) as anticipated by Houben et al. (US 5,919, 216, hereinafter "Houben") or, in the alternative, under 35 U.S.C. 103(a) as obvious over Houben in view of Klettner (US 5,031,617, hereinafter "Klettner").

5. In regards to claim 52, Houben discloses the essential features of the claimed invention, including an implantable electrode for applying an electric field to a pancreas (104), and circuitry that electrifies the electrode in a manner which generates an electric field that significantly reduces elevated blood glucose levels and applies the field also when levels are not elevated (col. 7, line 58). Because no baseline is defined to further limit "elevated," this term can be interpreted as the peak blood glucose level. Any stimulation after departure from this peak value meets the claim language. Since the body's response cannot be step-wise (i.e. the blood glucose level will decrease over some period of time during stimulation), and feedback only occurs at 1-2 minute intervals, Houben's device will inherently provide stimulation when glucose levels are not elevated (at the peak level).

6. Alternatively, Houben discloses the essential features of the claimed invention except for applying the glucose-lowering field also when glucose levels are not elevated. Klettner teaches providing glucose-lowering stimulation also when glucose levels are not elevated (Table 2) to provide the predictable results of aggressive treatment that quickly returns blood glucose to acceptable levels. Therefore, it would

have been obvious to one having ordinary skill in the art at the time the invention was made to modify Houben's invention by providing glucose-lowering stimulation also when glucose levels are not elevated to provide the predictable results of aggressive treatment that quickly returns blood glucose to acceptable levels.

7. In regards to claims 53 and 54, the device is a closed-loop/semi-open loop system that over stimulates in cases of doubt by providing a relatively long stimulation series without feedback (col. 7, line 58).

8. In regards to claim 81, the circuitry reduces insulin secretion (col. 9, line 45).

9. In regards to claim 82, the device is programmed with a knowledge of chemical-based insulin therapy provided to said pancreas (col. 10, line 50).

10. In regards to claims 83-85, the device comprises a glucose sensor to determine a need for acute insulin response (col. 7, line 37).

11. In regards to claim 86, the electrode is adapted for attachment to the pancreas (Fig. 10).

12. Claims 55, 79, 80, 87, and 102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houben (or Houben in view of Klettner). Houben (or Houben in view of Klettner) discloses the essential features of the claimed invention except for an open loop system, compensating by reducing glucagon secretion, or an electrode adapted for attachment to a muscular organ. It is well known in the art to provide open loop systems to conserve processor resources and battery life when controlling variables that do not require extremely precise control; to compensate by reducing glucagon levels to modify blood glucose levels faster than by modifying insulin alone; and to

provide an electrode adapted for attachment to a muscular organ to stimulate the pancreas with the easier implantation route of the gastrointestinal tract. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Houben's (or Houben in view of Klettner's) invention by providing an open loop system to conserve processor resources and battery life when controlling variables that do not require extremely precise control; to compensate by reducing glucagon levels to modify blood glucose levels faster than by modifying insulin alone; and to provide an electrode adapted for attachment to a muscular organ to stimulate the pancreas with the easier implantation route of the gastrointestinal tract.

13. In regards to claims 101 and 102, Houben (or Houben in view of Klettner) discloses the claimed invention, including reducing glucose/insulin secretion, but does not disclose expressly the 20% reduction. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the invention as taught by Houben (or Houben in view of Klettner) with the 20% reduction in glucose/insulin levels because applicant has not disclosed that a 20% reduction provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the device taught by Houben (or Houben in view of Klettner) because both inventions lower blood glucose/insulin levels by a user-desired amount. Therefore, it would have been an obvious matter of design choice to modify the specific value of glucose/insulin-lowering to obtain the invention as specified in the claims.

14. Claims 101 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houben in view of Klettner. Houben (or Houben's modified invention) discloses the essential features of the claimed invention except for a field that reduces elevated blood glucose levels by at least 20%. Klettner teaches a method of lowering elevated blood glucose levels by at least 20% (Tables 1 and 2) to provide the predictable results of providing normal glucose control to a patient. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Houben's invention (or Houben's modified invention) by lowering elevated blood glucose levels by at least 20% to provide the predictable results of providing normal glucose control to a patient.

Response to Arguments

15. Applicant's arguments filed 1/7/2008 have been fully considered but they are not persuasive. Applicant argued that Houben does not disclose a field that is applied also when glucose levels are not elevated, and cited Houben's disclosure that hypoglycemia is to be avoided. Please see the new grounds of rejection above, necessitated by amendment. Further, the claim language does not establish a threshold defining "elevated." Thus, Houben's discussion of hypoglycemia does not pertain to the claim language because the claim does not require stimulation during hypoglycemia, but only when the glucose level is not "elevated." Similarly, claims 53's and 54's limitations of over-stimulation and relatively long stimulation lack a baseline. Thus, stimulation that causes departure from the peak glucose level is over-stimulation and 1-2 minute stimulation intervals are relatively long compared to, e.g., 1 second intervals. Applicant

further objected to Examiner's lack of cited art for the previous rejections based on well-known features. However, teachings of these features were provided in the "Conclusion" section of the previous Office Action, and are provided again below.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Marchal et al. (US 6,853,862) is an example of a teaching of stimulating the pancreas via the gastrointestinal tract, Sun (US 6,122,536) is one of many teachings of modifying glucagon levels to modulate blood glucose levels, and Pfeiler et al. (US 5,558,640) is one of many teachings of open loop control.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Michael Kahelin/
Examiner, Art Unit 3762